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AMENDMENT NO._____

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Signature of Sponsor

AMEND Senate Bill No. 979* House Bill No. 1124

by deleting all language following the enacting clause and by substituting instead the following:

Section 1. Tennessee Code Annotated, Title 71, Chapter 1, is amended by adding Sections 2 through 8 of this act as a new part:

Section 2. This act shall be known and may be cited as the "TennCare Drug Formulary Accountability Act".

Section 3. The Bureau of TennCare (hereinafter referred to as the Bureau) shall conduct an independent clinical analysis of the drug formulary of each managed care organization (hereinafter referred to as MCO). Such independent study shall:

(1) incorporate a medical and pharmaceutical advisory committee comprised of persons not employed by the State of Tennessee, MCOs or pharmacy benefits managers (hereinafter referred to as PBMs) responsible for the current formularies, and who have no business-related conflict of interest; participation by TennCare health practitioners shall not constitute a conflict of interest;

(2) be completed no later than September 30, 1997; and

(3) be reported, upon completion, to the legislative TennCare Oversight Committee (hereinafter referred to as the Oversight Committee).

Section 4.

(a) The Bureau, in conjunction with the TennCare Pharmaceutical Care Policy Board, created pursuant to Section 5 of this act, shall develop a process for formulary development and management. The process shall address in detail:

(1) the required participants in formulary decision-making, using the following criteria:

(A) Any formulary developed by an MCO or PBM must be developed and updated by a panel of practicing TennCare physicians (including specialists as well as primary care practitioners), pharmacists, and may include other individuals with expertise or interest in the use of outpatient prescription drugs as part of a comprehensive program for patient care.

(B) If the formulary committee is organized or supervised by a PBM, its members shall be individuals who are not government employees and have no business-related conflict of interest.

(C) If the formulary committee is organized or supervised by an MCO, its members shall not be owners, employees, agents, contractors, or have any other financial interest with the MCO.

(D) Nothing in this subsection shall preclude participation by practicing TennCare physicians, pharmacists, and other TennCare health practitioners.

(E) The list of committee members shall be on file with the Bureau and the Board of Pharmacy.

(2) the factors to be considered and the factors, if any, that may not be considered in decisions affecting the formulary;

(3) procedures to guarantee input by practicing TennCare physicians;

(4) the minimum frequency for formulary revisions;

(5) disclosure of information to TennCare physicians and enrollees; and

(6) outcomes data collection, verification, and reporting by MCOs to the Bureau and consumers.

(b) The process for formulary development and management must be approved by the TennCare Pharmaceutical Care Policy Board and reviewed by the Oversight Committee. Such review shall occur no later than December 15, 1997.

(c) Following review by the Oversight Committee, the Bureau shall adopt the formulary development and management process as an administrative rule and/or as a standard provision in contracts with MCOs. MCOs must demonstrate compliance with the process as a condition for utilizing a restricted formulary. Absent compliance with the process, MCOs must allow physicians to prescribe using an open formulary.

Section 5. The TennCare Pharmaceutical Care Policy Board shall be a statewide independent board, appointed by the Commissioner of Health. Membership shall include:

(a)(1) Three (3) practicing TennCare pharmacists who practice at pharmacy practice sites as defined by the Tennessee Board of Pharmacy, selected from a list submitted by the decision-making board of the Tennessee Pharmacists Association.

(2) Four (4) individuals licensed and actively engaged in the practice of medicine in Tennessee under Title 63, Chapter 6, and who are TennCare

practitioners, selected from a list submitted by the Tennessee Medical Association.

(3) One (1) individual with expertise in therapeutic pharmacology who is neither a practicing physician nor a practicing pharmacist, selected from a list submitted by the Pharmaceutical and Research Manufacturers of America. This individual must be a resident of the state of Tennessee.

(4) One (1) individual with expertise in managed health care selected from a list submitted by the Tennessee Association of HMOs.

(b) Members shall not be government employees and shall have no business-related conflict of interest. Participation by TennCare health practitioners shall not constitute a conflict of interest.

(c) The Commissioner of Health may reject any or all recommendations, in which case the nominating process shall continue until appointments are finalized by the Commissioner.

(d) The initial list of nominees shall be submitted to the Commissioner of Health by September 1, 1997; final appointments shall be no later than October 1, 1997.

(e) Members shall be appointed for three-year terms, and initial appointments shall be staggered.

(f) In addition to assisting the Bureau, as described in Section 4(a), the Board shall be responsible for establishing policies and procedures that direct MCOs in the following:

(1) solicitation of input from patients and other parties affected by MCO decisions;

(2) evaluation of new drugs and biologics;

(3) restrictions on access to medications; and

(4) override of access restrictions.

Section 6. The Bureau shall require any MCO utilizing a restricted formulary to include in its prior approval and medical necessity procedures the following:

(a) The initial denial of a physician request can be made only by a physician reviewer.

(b) The physician must have the opportunity to appeal an initial denial by a faxed request for appeal, stating the physician's reasons for requesting the drug and attaching any information the treating physician wishes to have considered.

(c) All appeals must be reviewed by a physician of the same specialty as the requesting physician.

(d) In the case of an ultimate denial, the MCO must provide a written notice of denial stating the reasoned justification for the denial.

Section 7. The Bureau shall review the pharmacy benefits information distributed to enrollees and require network providers to conform to Bureau regulations and contract provisions. The MCO's handbook shall inform enrollees that prescription drugs are available and shall include each of the following items:

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(1) Limitations - Unless an open formulary is used, the handbooks should mention that the formulary used may require prior authorization or proof of medical necessity before a patient can obtain certain medications, even if the medications are prescribed by the patient's physician.

(2) Exclusions - Examples of drugs that are excluded (e.g. over-the-counter drugs and drugs for cosmetic purposes).

(3) Deductibles and Co-Payments - Should be mentioned in the pharmacy benefits section.

(4) Special Fees - Handbooks should inform enrollees they must pay for medications that are:

(A) not on the formulary;

(B) not authorized via prior approval; or

(C) not authorized for medical necessity.

Section 8. This act shall take effect upon becoming law, the public welfare requiring it.